DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0116]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910–0363)—Extension

The veterinary feed directive (VFD) drugs section of the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) established a new class of restricted feed use drugs that may be distributed without invoking State pharmacy laws. In order to implement the VFD drugs section of the ADAA, FDA issued regulations (65 FR 76924, December 8, 2000) that impose reporting and recordkeeping requirements on veterinarians, distributors of animal feeds containing VFD drugs, and clients using medicated feeds containing VFD drugs. All distributors of animal feed containing VFD drugs must notify FDA of their intent to distribute animal feed containing a VFD drug, and must maintain records of the distribution of all animal feeds containing VFD drugs (21 CFR 558.6).

In the **Federal Register** of April 30, 2002 (67 FR 21252), the agency requested comments on the proposed collection of information. FDA received one comment.

The comment asked if the proposed collection of information was necessary for the proper performance of FDA functions and whether the information will have practical utility. The answer is yes. As detailed, the VFD regulation ensures protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

Respondents to this collection of information are veterinarians, distributors of animal feeds containing VFD drugs, and clients using medicated feeds containing VFD drugs.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	0.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	1,500	1	500	0.25	125
558.6(d)(1)(iv)	20	1	20	0.25	5
558.6(d)(2)	1,000	5	5,000	0.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total					95,133

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(3)	5,000	75	375,000	.0167	6,263
Total					25,051

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on agency communication with industry. Other information needed to calculate the total burden hours are derived from agency records and experience.

Dated: August 13, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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